Shanghai Phoenix Medical Equipment CO., LTD.
NO.188 Zhongfa Road,Zhujing Industrial Park,Jinshan District,Shanghai China
Tel: 086-021-67221555 Fax:086-021-67221999
E-mail:ph@phoenixmed.com.cn

" 510(k) SUMMARY "

K130848

Submitter's Name: *Shanghai Phoenix Medical Equipment Co., Ltd.*
No.188 Zhongfa Road,Zhujikng Industrial Park, Jinshan District, Shanghai, China, 201500

Date summary prepared: March 18, 2013

Device Name:

Proprietary Name:	Shanghai Phoenix Mechanical Wheelchair
Model name:	PHW954LGC for Aluminum Framework PHW902BC for Steel Framework
Common or Usual Name:	Mechanical Wheelchair
Classification Name:	Mechanical Wheelchair, Class I,
Regulation Number:	21 CFR 890.3850
Product Code:	IOR

Contact person:

Dr. JEN, KE-MIN
TEL: +886-3-5208829 FAX: +886-3-5209783
Email: ceirs.jen@msa.hinet.net

Indications for Use:

The device is intended for medical purposes to provide mobility to persons restricted to a seated position.

Description of the device:

The Shanghai Phoenix Mechanical Wheelchair is indoor / outdoor wheelchair that has a base with four-wheeled with a seat. The device can be disassembled for transport and it is foldable easily. The device uses a standard sling type back and seat, the upholstery fabric meets the resistant to ignition source smouldering cigarette, and match flame equivalent.

Literature for Performance Testing:

Shanghai Phoenix Mechanical Wheelchair meets the applicable performance requirements as specified in ANSI/RESNA WC vol. 1 and ISO 7176 Wheelchair series relevant standards including:

- ISO7176-1 Wheelchairs - Part 1: Determination of Static Stability, 1999.
- ISO7176-3 Wheelchairs - Part 3: Determination of effectiveness of brakes, 2003.
- ISO7176-5 Wheelchairs - Part 5: Determination of overall dimensions, mass and maneuvering space, 2008.

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- ISO7176-7 Wheelchairs - Part 7: Measurement of seating and wheel dimensions, 1998.
- ISO7176-8 Wheelchairs - Part 8: Requirements and test methods for static, impact and fatigue strengths, 1998.
- ISO7176-11 Wheelchairs - Part 11: Test dummies, 1992.
- ISO7176-13 Wheelchairs - Part 13:Determination of coefficient of friction of test surfaces, 1989.
- ISO7176-15 Wheelchairs - Part 15:Requirements for information disclosure, documentation and labelling, 1996.
- ISO7176-16 Wheelchairs - Part 16:Resistance to ignition of upholstered parts -- Requirements and test methods, 1997.
- ISO7176-22 Wheelchairs - Part 22:Set-up procedures, 2000.
- EN 12183 Manually propelled wheelchairs _ Requirements and test methods, 1999.
- EN 1021-1 /-2 Assessment of the ignition of upholstered furniture, 2006.

Materials used in the main supporting features of the device:

- 7000 series aluminum for PHW954LGC Aluminum Framework.
- High-Quality SPCC Steel Pipe for PHW902BC Steel Framework.

Material in contact with patients:

- PVC Leather for seat.

Legally marketed device for substantial equivalence comparison:

KAIYANG Aluminum Wheelchair (K101998)

Summary for substantial equivalence:

All of the features, except for the sizes and supporting material, are the same. The small differences of the sizes between the two devices do not affect the safety or effectiveness. Furthermore, the steel material for the subject device shows more strength than the aluminum material used for the predicate device. Thus the subject device is substantially equivalent to the predicate device.

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Comparison Table

ITEMS	PREDICATE DEVICE	SUBJECT DEVICE
BRAND NAME	***KAIYANG***	**Shanghai Phoenix**
MANUFACTURER	*Guangdong Kaiyang Medical Technology Co., Ltd.*	Shanghai Phoenix Medical Equipment Co., Ltd.
MODEL NO	*KAIYANG Aluminum Wheelchair*	Mechanical Wheelchair PHW954LGC Aluminum Framework PHW902BC Steel Framework
510K NO	***K101998***	**K130848**
INTENDED USE	*The device is intended for medical purposes to provide mobility to persons restricted to a sitting position.*	SAME
FRAME		
Seat width	*18.1"~25.1"*	18.1"
Cross brace	*YES*	SAME
Seat height	*16.2"*	20.0"
Full length	*1050 mm*	1180 mm
Full width	*650 mm*	670 mm
Full height	*920 mm*	920 mm
Backrest height	*un-adjustable*	SAME
Reclining backrest	*fixed*	SAME
Seat sling	*padded nylon*	SAME
Frame colors	*Black, Blue*	Silver white
ARMREST		
Arm pad	*Padded*	SAME
Flip back	*YES, detachable*	SAME
Height-adjustable	*adjustable*	SAME
HANGERS		
Swing-away	*YES*	SAME
Elevating leg rest	*YES*	SAME
Articulating leg rest	*YES*	SAME
Footplate style	*Padded*	SAME
Heel loop	*No*	SAME
Footrest angle	*10^0*	SAME
REAR AXLE		
Offset axle	*YES*	SAME
Quick-release axle	*YES*	

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ITEMS	PREDICATE DEVICE	SUBJECT DEVICE
REAR WHEEL **Size** **Tire type** **Handrim material**	*7.5"* *Pneumatic* *Aluminum composite*	24" Pneumatic Aluminum composite
CASTERS **Size** **Tire type**	*5~8"* *Solid*	7" Solid
WHEEL LOCK	*Pull-to-Lock*	SAME
WEIGHT CAPACITY	*100 Kgs / 220 lbs*	SAME
WEIGHT OF CHAIR	*17.5~ 21 kgs*	SAME (19.0 kgs / 41.8 lbs)
STABILITY TEST	*ISO 7176 series standards*	SAME
WARRANTY	*12 months for the main parts* *(The chair side frames are guaranteed for 5 years from the date of purchase.)*	SAME
OPTIONAL ACCESSORIES **Anti-tipper** **Rear stepper** **Fold down push handle**	 *YES* *YES* *YES*	SAME

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 12. 2013

Shanghai Phoenix Medical Equipment Co., Ltd.
Ke-Min Jen, Official Correspondent
No. 188 Zhonfga Road
Zhujing Industrial Park
Jinshan District, Shanghai
China 201500

Re: K130848
Trade/Device Name: Shanghai Phoenix Mechanical Wheelchair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I
Product Code: IOR
Dated: September 15, 2013
Received: September 24, 2013

Dear Ke-Min Jen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130848

Device Name: Shanghai Phoenix Mechanical Wheelchair

Indications For Use:

The device is intended for medical purposes to provide mobility to persons restricted to a sitting position.

Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ___X___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Joyce M. Whang -S